



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/680,935

10/02/2003

David Bar-Or

4172-81

7439

22442

7590

04/23/2008

SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER

JUEDES, AMY E

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

04/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/680,935	Applicant(s) BAR-OR ET AL.	
	Examiner AMY E. JUEDES	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 164, 177, 221, 231 and 284-306 is/are pending in the application.
- 4a) Of the above claim(s) 286, 292, 294-296, 299, 301, 304 and 306 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 164, 177, 221, 231, 284, 285, 287-291, 293, 297, 298, 300, 302, 303 and 305 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

Art Unit: 1644

DETAILED ACTION

1. Applicant's amendment and remarks, filed 3/4/08, are acknowledged.

Claims 164, 177, 221, 231, and 284-306 are pending.

2. Claims 286, 292, 294-296, 299, 301, 304, and 306 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 164, 177, 221, 231, 284, 285, 287-291, 293, 297, 298, 300, 302-303, and 305 are being acted upon.

3. The objection to the drawings is withdrawn in view of Applicant's submission of corrected drawings.

4. The objection for lack of sequence compliance is withdrawn in view of Applicant's submission of the corrected CRF.

5. Applicant's information disclosure, filed 10/29/07, is acknowledged. However, citations 11 and 17 have been lined through since they have not been identified by date of publication, as is required. See MPEP § 609.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 164, 177, 221, 231, 285, 287-290, 293, 297, 300, 302, and 305 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written description to demonstrate that applicant was in possession of the claimed genus of antibodies specific for "post-translationally modified proteins" or "post-translationally modified" albumin and "cysteinylation proteins".

Art Unit: 1644

As set forth previously, The instant claims are drawn to antibodies specific for "post-translationally modified" or "cysteinylation" proteins. This might encompass antibodies specific for virtually any protein, including cytokines, receptors, hormones, etc. This encompasses a wide range of structurally different antibodies that bind to structurally and functionally different proteins. Furthermore, the claims encompass antibodies specific for any type of post-translational modification of virtually any protein. This might include proteins modified by acylation, methylation, biotinylation, sulfation, ubiquitination, citrullination, etc. Furthermore, even when the claims are limited to antibodies specific for "post-translationally modified" albumin, this still encompasses a wide range of structurally different antibodies specific for a variety of modified forms of albumin, as discussed above. While the specification does disclose antibodies specific to several species of protein, including albumin, S100, troponin I, etc., as well as several types of post-translational modifications, including cysteinylation and phosphorylation, this is not sufficiently representative of the virtually unlimited number of structurally and functionally distinct antibodies encompassed by the instant claims. Thus, one of skill in the art would conclude that the specification fails to provide adequate written description to demonstrate that Applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F. 3d 1559, 43, USPQ2d 1398.

Applicant's arguments filed 3/4/08 have been fully considered, but they are not persuasive.

Applicant argues that the specification has provided an extensive and detailed description of the invention, including many specific examples of proteins and post-translational modifications.

The instant claims encompass antibodies specific to virtually any post-translationally modified protein. The specification does not disclose a common structure or function that is shared by the proteins, and thus, the claims encompass antibodies specific for a virtually unlimited number of structurally and functionally different protein. The specification discloses approximately 25 different proteins. However, this is not representative of a genus of antibodies specific for virtually any protein. Likewise, the claims encompass antibodies to proteins such as albumin with any post-translational modification. The specification on page 9 discloses that "post-translational" modification means any modification of a protein that occurs after peptide bond formation. The specification discloses 7 examples of said modifications, including phosphorylation and cysteinylation. However, the instant claims encompass antibodies specific to virtually any modified protein. These "modifications" would result in structural changes to the proteins. For example, the claims might encompass digested proteins or protein fragments, or other modification including biotinylation, sulfation, ubiquitination, citrullination, etc. The examples disclosed by

Art Unit: 1644

the specification are not sufficiently representative of the structurally and functionally different antibodies specific for any modified protein.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 164 and 284-285 stand rejected under 35 U.S.C. 102(b) as being anticipated by Doyen et al., 1985, as evidenced by Glowacki et al., 2004.

As set forth previously, Doyen et al. teach monoclonal antibodies specific for human serum albumin. Doyen et al. also teach that the antibodies are specific for several different albumin epitopes, including epitopes residing between residues 124-298, residues 308-496, and residues 496-585 (see page 8 in particular). As evidenced by Glowacki et al., albumin exists in the circulation as two major forms, including albumin-Cys34-S-S-Cys (i.e. cysteinylated albumin). Thus, cysteinylated albumin is identical to albumin, except for the presence of a disulphide bonded cysteine residue at amino acid residue 34. Therefore, the antibodies taught by Doyen et al. would inherently bind to cysteinylated albumin, since it comprises an identical amino acid sequence to albumin over amino acid residues 124-598. Doyen et al. also teach using the antibodies for various immunological detection assays.

Applicant's arguments filed 3/4/08 have been fully considered, but they are not persuasive.

Applicant argues that Doyen et al. does not teach antibodies specific for cysteinylated albumin, since Doyen et al. does not teach antibodies that will react selectively with cysteinylated albumin and not with non-cysteinylated albumin.

The instant claims are not limited to antibodies that bind to cysteinylated albumin without binding to non-cysteinylated albumin, as asserted by Applicant. The instant claims are drawn to antibodies specific for cysteinylated albumin. An antibody that binds to a protein is specific for said protein. The antibodies of Doyen et al. would bind to cysteinylated albumin, and therefore can be considered specific for cysteinylated albumin.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1644

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 164, 177, 221, 231, 284-285, 287-291, 293, 297-298, 300, 302-303, and 305 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Doyen et al., 1985 and Glowacki et al., 2004, in view of US Patent 5,198,340.

As set forth previously, The teachings of Doyen et al. and Glowacki et al. are described above.

They do not teach a kit comprising the albumin specific antibodies.

The '340 patent teaches that, as a matter of convenience, antibodies for immunological detection assays can be packaged in the form of a kit, along with instructions for carrying out the assay.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide the albumin specific antibody used for immunological detection assays, as taught by Doyen et al., as a part of a kit, as taught by the '340 patent. The ordinary artisan at the time the invention was made would have been motivated to do so since the '340 patent teaches the convenience of packaging reagents necessary for performing an assay together in the form of a kit. Furthermore, regarding the limitations of instructions specifying an intended use of the claimed kit (i.e. for diagnosing ischemia or multiple organ failure), where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art (see MPEP 2112.01).

Applicant's arguments filed 3/4/08 have been fully considered, but they are not persuasive.

Applicant argues that the cited references do not teach or suggest kits that can be used for the diagnosis of the specific disease or conditions of the instant claims.

The instructions of the instant claims specify an intended use of the claimed kit (i.e. for diagnosing ischemia or multiple organ failure). Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art (see MPEP 2112.01).

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the

Art Unit: 1644

extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600

/G.R. Ewoldt/
Primary Examiner, Art Unit 1644